Marked-up Version of Amended Claims under §1.121

1. (Amended) A topical lotion comprising:

about 0.005 to 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;

about 1.0 to 10.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof;

about 1.0 to 5.0 wt.% of at least one first skin conditioning agent;

about 5.0 to 15.0 wt.% propylene glycol;

[up to about 10.0] about 2.0 to 5.0 wt.% mineral oil or white soft paraffin; and

the balance in water.

2. (Amended) A topical lotion comprising:

about 0.005 to 1.0 wt.% fluticasone propionate;

about 3.0 to 7.0 wt.% of a C_{14}-C_{20} fatty alcohol, or mixtures thereof;

about 0.5 to 3.0 wt.% of at least one first skin conditioning agent;

about 0.25 to 2.0 wt.% of at least one surfactant;

about 7.0 to 12.0 wt.% propylene glycol;

[up to about 10] about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin; and

the balance in water.

3. (Amended) The lotion according to claim 1, further comprising [less than] up to about 5.0 wt.% dimethicone.

4. (Amended) The lotion according to claim 2, further comprising [less than] up to about 5.0 wt.% dimethicone.

5. (Amended) The lotion according to claim 1, [wherein said pharmaceutically acceptable ester of fluticasone is] comprising fluticasone propionate.

6. (Amended) The lotion according to claim 1, comprising:

about 0.05 wt.% fluticasone propionate,

about 5.0 wt.% cetostearyl alcohol,

about 1.0 wt.% isopropyl myristate,

about 1.0 wt.% dimethicone,

about 1.0 wt.% cetomacrogol,

about 10.0 wt.% propylene glycol

[less than about 0.30 wt.%] a preservative effective amount of imidurea, [less than about 0.20 wt.%] methyl paraben, [less than about 0.10 wt.%] and propyl paraben,

[about 0.05 wt.%] a buffering effective amount of anhydrous citric acid [(anhydrous),] and [about 0.08 wt.%] sodium citrate, and

the balance in purified water.

9. (Amended) The lotion according to claim 2, [having the formula] comprising:

about 5.25 wt.% cetostearyl alcohol,

about 2.0 wt.% isopropyl myristate,

about 10.0 wt.% propylene glycol,

about 0.20 wt.% imidurea,

about 0.20 wt.% methyl paraben,

about 0.10 wt.% propyl paraben, and

the balance in purified water.

12. (Amended) [The] A topical lotion [according to claim 1,] free of mineral oil or white soft paraffin comprising:

about 0.005 to 1.0 wt.% fluticasone or a pharmaceutically acceptable salt or ester thereof;

about 1.0 to 10.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof;

about 1.0 to 5.0 wt.% of at least one first skin conditioning agent;

about 5.0 to 15.0 wt.% propylene glycol;

about 2.0 to 5.0 wt.% mineral oil or white soft paraffin; and,

the balance in water.

13. (Amended) [The] A topical lotion [according to claim 2,] free of mineral oil or white soft paraffin comprising:

about 0.005 to 1.0 wt.% fluticasone propionate;

about 3.0 to 7.0 wt.% of a C_{14}-C_{20} fatty alcohol, or mixtures thereof;

about 0.5 to 3.0 wt.% of at least one first skin conditioning agent;

about 0.25 to 2.0 wt.% of at least one surfactant;

about 7.0 to 12.0 wt.% propylene glycol;

about 2.0 to 5.0 wt.% mineral oil or white soft paraffin; and,

the balance in water.

14. (Amended) [Use of the lotion according to claim 1 to increase] A method of increasing [the] vasoconstrictor potency of [fluticasone] a topical lotion including fluticasone or a salt or ester thereof comprising the acts of:

providing 0.005 to 1.0 wt.% fluticasone or a pharmaceutically acceptable salt or ester thereof, and,

preparing a topical lotion by combining the fluticasone or pharmaceutically acceptable salt or ester thereof with about 1.0 to 10.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof, about 1.0 to 5.0 wt.% of at least one first skin conditioning agent, about 5.0 to 15.0 wt.% propylene glycol, about 2.0 to 5.0 wt.% mineral oil or white soft paraffin, and the balance water.

15. (Amended) [Use of the lotion according to claim 2 to increase the] A method of increasing vasoconstrictor potency of a topical lotion including fluticasone proprionate comprising the acts of:

providing 0.005 to 1.0 wt.% fluticasone propionate, and,

preparing a topical lotion by combining the fluticasone propionate with about 3.0 to 7.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof, about 0.5 to 3.0 wt.% of at least one first skin conditioning agent, about 0.25 to 2.0 wt.% of at least one surfactant, about 7.0 to 12.0 wt.% propylene glycol, about 2.0 to 5.0 wt.% mineral oil or white soft paraffin, and the balance water.

16. (Amended) A process for preparing [a] the topical lotion according to claim 1, comprising:

mixing the [ingredients recited in claim 1] fluticasone or pharmaceutically acceptable salt or ester thereof, fatty alcohol or mixtures thereof, first skin conditioning agent, propylene glycol, mineral oil or white soft paraffin, and water at an elevated temperature producing a lotion mixture; and

cooling said lotion mixture.

17. (Amended) A process for preparing [a] the topical lotion according to claim 1, comprising:

mixing the [ingredients] fluticasone or pharmaceutically acceptable salt or ester thereof, fatty alcohol or mixtures thereof, first skin conditioning agent, propylene glycol, mineral oil or white soft paraffin, and water [recited in claim 1] at an elevated temperature producing a lotion mixture; and

heating said lotion mixture mixture.

18. (Amended) A topical lotion comprising:

about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;

a thickening effective concentration of at least one thickener;

a conditioning effective concentration of at least one skin conditioning agent;

an emulsifying effective amount of a surfactant,

about 2.0 to 5.0 wt.% mineral oil or white soft paraffin, and

the balance in water.

19. (Amended) The lotion of claim 18, wherein the lotion has a 2-hour mean blanching score of at least about 2.1[, an AUC of at least about 26.7], and an average mean blanching of at least about 1.5.

21. (Amended) A method of treating a skin condition comprising:

providing a topical lotion [including] comprising about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof; about 1.0 to about 10.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof; about 1.0 to about 5.0 wt.% of at least one skin conditioning agents; about 5.0 to about 15.0 wt.% of propylene glycol; [less than about 10.0] about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin, and the balance in water; and,

applying the lotion to the skin having the skin condition.

23. (Amended) The [topical lotion] method of claim 21, wherein the topical lotion has a 2-hour mean blanching score of at least about 2.1[, an AUC of at least about 26.7,] and an average mean blanching of at least about 1.5.

24. (Amended) The method [lotion] of claim 21, wherein the topical lotion is chemically and physically stable for at least 6 months at 40°C.

REMARKS

Claims 1-24 are pending. Claims 1-24 stand rejected. The claims have been amended to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for the amendments is found in the application as originally filed. No new matter has been added. Applicants respectfully traverse the rejections and request reconsideration and withdrawal of the rejections.

Rejections Under 35 USC 112, Second Paragraph

Claims 14, 15, 19, 20, 23 and 24 stand rejected as being indefinite. Claims 14 and 15 have been amended to clearly recite a method comprising a plurality of acts. The rejection of claims 14 and 15 under 35 USC 101 has also been overcome by such amendments. Reconsideration and withdrawal of the rejections is requested.

Claims 23 and 24 stand rejected on the ground that the preamble lacks antecedent basis to independent claim 21. Applicants have amended claims 23 and 24 to recite a "method" in the preamble. Reconsideration and withdrawal of the rejections is respectfully requested.

Claims 19 and 23 stand rejected because the term "AUC" is unclear. Claims 19 and 23 have been amended to delete the phrase directed to the Area Under the Curve, or AUC. (See page 16, lines 12-19). Reconsideration and withdrawal of the rejections is respectfully requested.

Claims 20 and 24 also stand rejected as being indefinite on the ground that "chemically and physically stable" are relative terms. Applicants submit that the original language complies with 35 USC 112, respectfully traverse the rejections, and submit that one of ordinary skill understands what the phrase means. The specification clearly discloses that the invention concerns a therapeutic topical lotion, so one of ordinary skill would understand that claims 20 and 24 are directed to topical lotions that are

therapeutically stable for at least 6 months at 40°C. Reconsideration and withdrawal of the rejections is respectfully requested.

Rejections Under 35 USC 102(b)

Claims 1, 5, 16, 18, 21 and 22 stand rejected as being anticipated by WO 92/14472 (the '472 PCT). The '472 PCT discloses various lotion formulations, however only 10.00 %w/w white soft paraffin is disclosed. To anticipate a claims, a single reference must disclose each and every element of the claimed invention.

In contrast to the '472 PCT, the instant claims are directed to a topical lotion comprising "about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin." (See Claims 1, 18 and 21). Moreover, the instant specification discloses that the instant invention has improved vasoconstrictor potency, at least in part, by limiting or eliminating the presence of excessive occlusive agent, such as mineral oil. (See Page 1, lines 27-24).

Thus, the instantly claimed invention is patentably novel and nonobvious over the '472 PCT because the reference fails to disclose each and every element of the claimed invention. Reconsideration and withdrawal of the rejections is respectfully requested.

Rejections Under 35 USC 103(a)

Claims 2-4, 6-15, 17, 19, 20 and 23-24 stand rejected as being obvious over the '472 PCT, USPN 4,985,418 (the '418 patent) and the Gordon publication. To establish a prima facie case of obviousness, one or more properly combined references must teach each and every element of the claimed invention.

The '418 patent and the Gordon publication also fail to teach or suggest employing "about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin" or such low amounts of occlusive agent. The references also fail to motivate one of ordinary skill to employ no or low amounts of occlusive agents to

improve vasoconstrictor potency. Moreover, in view of the references, one of ordinary skill would not be properly motivated to employ 2-5 wt.% occlusive agent because not such suggestion is disclosed. Moreover, no prima facie case of obviousness is established by alleging optimization because to do so would only be motivated by an attempt "to try" which is insufficient and improper for purposes of obviousness.

Thus, the claimed invention is patentably nonobvious over the references because, *inter alia*, none of the references teach or suggest the instantly claimed amount of mineral oil or white soft paraffin. Reconsideration and withdrawal of the rejections is respectfully requested.

For the above reasons, Applicants respectfully traverse the rejections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

Date: 18 Oct 2001

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